

Notice of Allowability**Application No.**

09/762,724

Examiner

Jeanine A Goldberg

Applicant(s)

KOVACS ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 4/29/03.
2. ☒ The allowed claim(s) is/are 1-3,8-12 and 17-22.
3. ☒ The drawings filed on 09 February 2001 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- * Certified copies not received: _____.
5. ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
(a) ☐ The translation of the foreign language provisional application has been received.
6. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. ☐ CORRECTED DRAWINGS must be submitted.
(a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
1) ☐ hereto or 2) ☐ to Paper No. _____.
(b) ☐ including changes required by the proposed drawing correction filed _____, which has been approved by the Examiner.
(c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet.

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------|
| 1 <input type="checkbox"/> Notice of References Cited (PTO-892) | 2 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3 <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 4 <input checked="" type="checkbox"/> Interview Summary (PTO-413), Paper No. <u>0503</u> |
| 5 <input type="checkbox"/> Information Disclosure Statements (PTO-1449), Paper No. _____ | 6 <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 7 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | 8 <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9 <input type="checkbox"/> Other |

EXAMINER'S AMENDMENT

1. This action is in response to the papers filed April 29, 2003.
2. An extension of time under 37 CFR 1.136(a) is required in order to make an examiner's amendment which places this application in condition for allowance. During a telephone conversation conducted on May 28, 2003, Tanya Harding requested an extension of time for 1 MONTH(S) and authorized the Director to charge Deposit Account No. 02-4550. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.
3. The application has been amended as follows:
 - A) Claims 23, 24, 46 have been cancelled.
4. The following is an examiner's statement of reasons for allowance.

The claims are drawn to a method of detecting the presence of *Pneumocystis carinii* in a human biological sample by amplifying a highly conserved region selected from a nucleic acid comprising residues 2794-3042 of HMSGp1 (SEQ ID NO: 1), 2758-3006 of HMSGP3 (SEQ ID NO: 3), 2845-3090 of HMSGII (SEQ ID NO: 5), 2839-3084 of HMSGI4 (SEQ ID NO: 7), 2836-3081 of HMSG32 (SEQ ID NO: 9), 2809-3054 of HMSG33 (SEQ ID NO: 11), or 1-249 of HMSGP2 (SEQ ID NO: 15) and residues 2821-

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3072 of HMSG35 (SEQ ID NO: 13) with at least one oligonucleotide primer consisting of SEQ ID NO: 17 or 18 and detecting an amplified sequence.

The closest prior art teaches an alignment of amino acid sequences from msgI to msgIV and rat msg (Garbe, Infection and Immunity, August 1994). Given the alignment of the MsgI and MsgII regions, the nucleic acid sequence may be determined in Figure 5. While Garbe teaches specific regions conserved, Garbe does not teach SEQ ID NO: 17 and 18 are within these conserved regions. Therefore, the teachings of the 8 additional *P. carinii* sequences (SEQ ID NO: 1, 3, 5, 7, 9, 11, 13, 15) provide a new region conserved among the nucleic acids. Therefore, designing primers to this region, which was not previously known to be conserved among the species, would not have been obvious. Furthermore, there is no teaching in the art that would direct the ordinary artisan to design primers directed to nucleic acids consisting of SEQ ID NO: 17 and 18.

Therefore, the claimed invention is neither taught nor suggested by the art. Therefore, the claims are allowable.

5. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (703) 306-5817. The examiner can normally be reached Monday-Friday from 8:00 a.m. to 5:30 p.m.

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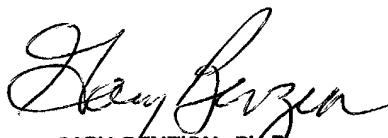
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax number for this Group is (703) 305- 3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

J. Goldberg
Jeanine Goldberg
May 28, 2003


GARY BENZION, PH.D.
SUPERVISORY PATENT EXAMINER
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